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Diana A. Mark

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## COMMENTS

### ALL ANIMALS ARE EQUAL, BUT SOME ARE BETTER THAN OTHERS: PATENTING TRANSGENIC ANIMALS

Ours is a time of intense self-doubt, corroding confidence, and crippling resolve; a time of troubled present and ominous future; a time of strange clouds and sudden shadows seen in a fading light with cracking nerve. And hence it is not surprising that so great a triumph as man's discovery of the molecular basis of inheritance should provoke fear instead of joy, breed suspicion instead of zest, and spawn the troubled anguish of indecision instead of the proud relief of understanding.<sup>1</sup>

R. Sinsheimer

Since the discovery of the structure of DNA by Watson and Crick in 1953, remarkable advances have been made in the field of biochemistry. Science has progressed from cracking the genetic code to understanding the operation and functions of genes. Today, it is possible to splice the genes of animals and manipulate them to produce essentially a new animal, one with unique characteristics that would never occur naturally within a particular species. These expanding capabilities permit refinement of scientific animal modeling,<sup>2</sup> a process crucial to progress in medical and genetic research, and provide future promise for the eradication of diseases such as AIDS and heart disease.<sup>3</sup>

The popular word in biochemistry today is "transgenic." Transgenic refers to the manipulation and transfer of at least one specific gene sequence (i.e., a DNA molecule) into the genome<sup>4</sup> of a laboratory animal, thus pro-

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1. R. SINSHEIMER, *ETHICAL ISSUES IN HUMAN GENETICS* 341 (1972).

2. Animal modeling is a scientific procedure that causes a laboratory animal to display a particular human illness or disease. Gene splicing allows a scientist to insert gene(s) into the laboratory animal which causes that animal to develop a desired human disease, thereby producing a convenient model for laboratory investigation. Council on Scientific Affairs, *Animals in Research*, 261 J. A.M.A. 3602, 3602-06 (1989) (providing examples and explanations of animal models in the laboratory).

3. Auerbach, *Animal Patenting: Ethics, Enablement and Enforcement*, 1989 BIOTECH. PAT. CONF. WORKBOOK 24, 25 (1989) (publication of the American Type Culture Collection, 12301 Parklawn Drive, Rockville, Maryland 20852, (800) 638-6597).

4. A genome includes all the genes of an organism. There are twenty-three pairs of

ducing what has been termed a transgenic animal.<sup>5</sup> On April 12, 1988, the United States Patent and Trademark Office (PTO) granted its first, and to date only, transgenic animal patent.<sup>6</sup> This transgenic mouse patent is held by Harvard University<sup>7</sup> and covers the following: "A transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage."<sup>8</sup>

Transgene manipulation provides a convenient animal model for scientists to study more easily certain human cancers. While such experimentation will undoubtedly benefit mankind, it remains controversial; unanswered ethical and legal questions will continue to accompany the granting of patents for the new technology.

A United States patent is a property right awarded to an inventor for seventeen years, giving the inventor the exclusive right to make, use, and sell the invention in return for the public disclosure of the inventor's procedures for creating the invention.<sup>9</sup> For practical purposes, a patent is essentially an exchange between an inventor and the American public. In return for the grant of exclusivity, the inventor publicly discloses the discovery or invention, as well as the formula for its creation. This system encourages research and development by inducing inventors to invest in experimentation and in-

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chromosomes in a human being—all the genes necessary for humans to function are included twice within the human being. Each set of genes is called a haploid set of chromosomes. The genome, then, is one full set of genes within a haploid complement of chromosomes. R. WALLACE, J. KING & G. SANDERS, *BIOLOGY: THE SCIENCE OF LIFE* 1084 (1981) [hereinafter *THE SCIENCE OF LIFE*].

5. Barinaga, *Making Transgenic Mice: Is It Really That Easy?*, 245 *Sci.* 590, 590, 591 (1989) [hereinafter *Making Transgenic Mice*]. The most common method for producing transgenic animals is the microinjection method. This procedure involves the removal of fertilized eggs from an animal and the injection of foreign DNA containing the desired gene(s) sequence into the nucleus of each egg with a super-fine needle. These eggs are then surgically implanted into surrogate mothers for development. This labor-intensive technique requires very specialized equipment and is both expensive and difficult to master. *Id.* at 590. Transgenic technology differs from conventional, classical breeding methods for producing animals with desired traits because there is an added "capacity . . . to introduce and express a *heterologous* gene sequence (i.e., one not derivable from the same species as the transgenic animal) in a second animal." Auerbach, *supra* note 3, at 25 (emphasis in original).

6. U.S. Pat. No. 4,736,866 (1988).

7. The mice were developed by Philip Leder and Timothy Stewart, of Harvard University and Genentech, respectively. *Id.*

8. U.S. Pat. No. 4,736,866 (1988). An oncogene is a cancer-producing gene.

The first "oncomice" . . . carry the ras oncogene, which has been shown to be common in a variety of human cancers, plus a mouse mammary tumor virus promoter which ensures that the oncogene is activated in breast tissue so that the mice develop a human breast cancer within a few months of birth.

Anderson, *Oncomouse Released*, 336 *NATURE* 300, 300 (1988).

9. A patent does not necessarily confer the right to sell. 35 U.S.C. § 154 (1982).

vestigation.<sup>10</sup> The patent-granting power vested in Congress<sup>11</sup> has been passed to the United States Patent and Trademark Office (PTO) through the enactment of three statutes: the Patent Act of 1790;<sup>12</sup> the Plant Protection Act of 1930;<sup>13</sup> and the Plant Variety Protection Act of 1970.<sup>14</sup>

The present debate over animal patenting was perhaps best foreshadowed by Donald J. Quigg, former Commissioner of Patents. In the PTO's landmark 1987 announcement that it would consider patent applications for "nonnaturally-occurring non-human multicellular living organisms, including animals,"<sup>15</sup> Quigg asked, "I know I'm not supposed to get on a soapbox,

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10. Patentable subject matter is defined as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . . subject to the conditions and requirements of this title." 35 U.S.C. § 101 (1982).

11. U.S. CONST. art. I, § 8 states that Congress shall have the power to "promote the Progress of Science and the useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

12. 35 U.S.C. § 100 (1982).

13. 35 U.S.C. § 161 (1982).

14. 7 U.S.C. §§ 2321-2583 (1982).

15. *Nonnaturally Occurring Non-Human Animals Are Patentable Under § 101*, 33 PAT. TRADEMARK & COPYRIGHT J. 663, 664 (1987) [hereinafter *Patentable Under § 101*]. Former Commissioner Quigg also stated:

A decision by the Board of Patent Appeals and Interferences in *Ex parte Allen*, [2] USPQ [2d 1425] (Bd. App. & Int. April 3, 1987), held that claimed polyploid oysters are nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. 101. The Board relied upon the opinion of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980)[;] as it had done in *Ex parte Hibberd*, 227 USPQ 443 (Bd. App. & Int., 1985), as controlling authority that Congress intended statutory subject matter to "include anything under the sun that is made by man." The Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law. See e.g., *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948); *American Fruit Growers v. Brogdex*, 283 U.S. 1, 8 USPQ 131 (1931); *Ex parte Grayson*, 51 USPQ 413 (Bd. App. 1941).

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed

but how can anybody say this kind of development is unethical or wrong?"<sup>16</sup> Today, the granting of patents for genetically engineered animals involves not only ethical and legal issues, but also presents economic and environmental concerns.<sup>17</sup>

As a federal agency, the PTO possesses the power to establish rules and policies, yet many question its authority to enact a rule with such complex and far-reaching consequences.<sup>18</sup> The decision to allow patents for the transgenic products of biotechnology is fraught with yet unfathomable complexities. Therefore, it is neither appropriate nor wise to reach a final determination on the animal patenting issue until after these complexities have been contemplated and deliberated exhaustively.<sup>19</sup>

This Comment will discuss the practical uses of transgenic animals in genetic research, medicine, and agriculture. It will also describe the issues associated with patenting higher organisms, such as farm animals and laboratory mice, and suggest the possible ramifications of this procedure. Further, this Comment will explain how the PTO and the Supreme Court have arrived at the conclusion that transgenic animals are patentable subject matter. Finally, it will explore the void in current legislation, the status of congressional efforts in this area, and the need for a moratorium to both halt the granting of animal patents and extend indefinitely the time for a final resolution of transgenic animal patenting.

## I. EVOLUTION OF THE TRANSGENIC ANIMAL: PRACTICAL USES OF TRANSGENIC ORGANISMS

Deoxyribonucleic acid (DNA),<sup>20</sup> the genetic material of almost all orga-

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subject matter is directed to a non-human "nonnaturally occurring manufacture or composition of matter—a product of human ingenuity" (*Diamond v. Chakrabarty*), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subject matter.

Commissioner's Notice of Apr. 7, 1987, 1077 OFF. GAZ. PAT. OF. 24 (Apr. 21, 1987).

16. *Patentable Under § 101*, *supra* note 15, at 664; U.S. CONG., OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE—SPECIAL REPORT, OTA-BA-370, 125 (Washington, D.C., U.S. Government Printing Office, Apr. 1989).

17. *See infra* text accompanying notes 47-59 (animal rights); notes 60-76 (agricultural industry); notes 77-80 (religious concerns); notes 81-85 (environmental concerns); notes 86-93 (humanity).

18. *See Animal Legal Defense Fund v. Quigg*, 710 F. Supp. 728 (N.D. Cal. 1989) (holding that in the promulgation of its 1987 rule, the Patent and Trademark Office did not exceed its authority), *dismissed*, 900 F.2d 195 (9th Cir. 1990) (case transferred to Fed. Cir.).

19. *See generally Transgenic Animal Patent Reform Act of 1989: Hearings on H.R. 1556 Before the Subcomm. on Courts, Intellectual Property, and the Administration of Justice of the House Comm. on the Judiciary*, 101st Cong., 1st Sess. 246 (1989) [hereinafter *Hearings on H.R. 1556*] (statement of Steven M. Wise, President, Animal Legal Defense Fund, Inc.).

20. *See infra* note 22.

nisms,<sup>21</sup> contains information that directs cellular activity and ultimately determines physical traits. DNA can therefore be characterized as the data base of an organism. DNA is also responsible for transmitting all of its information by duplicating itself and passing down identical copies to the next generation of cells.

The structure of DNA resembles that of a very long and twisted ladder with thousands to millions of rungs.<sup>22</sup> Genes, the basic units of heredity, are segments of each DNA molecule. Most genes contain a "program"<sup>23</sup> that determines the structure of a protein.<sup>24</sup> The genetic message in DNA codes for the particular type of protein to be synthesized and determines when this synthesis will occur and the amount of the protein to be produced. The visible result of the genetic program, then, is a protein responsible for a particular characteristic of any given organism, including hair color, physical capacities, and intelligence.

Genetic engineering of transgenic organisms is accomplished by the transfer of genes from one organism into another.<sup>25</sup> By manipulating genes in this way, new organisms may be created and endowed with the novel traits or unique capabilities that a scientist has specifically chosen to produce in

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21. THE SCIENCE OF LIFE, *supra* note 4, at 1080 (DNA not genetic material for RNA viruses); see *infra* note 23 (general discussion of RNA).

22. The basic unit of DNA is called a nucleotide which consists of a phosphate, a 5-carbon sugar (deoxyribose), and one of four different nucleotide bases: thymine, cytosine, adenine, or guanine. DNA is composed of two long chains of nucleotides. The backbone of each chain consists of alternating sugars and phosphates. The nucleotide bases are like the rungs of a ladder that hold the two backbones together. Each rung consists of two nucleotide bases paired together, one from each side of the chain. The structure of the bases allows guanine to pair only with cytosine, and thymine to pair only with adenine. These two strands of DNA are wound around each other in the double helix configuration. THE SCIENCE OF LIFE, *supra* note 4, at 183-91 (discussing DNA structure and replication).

23. DNA codes for the production of proteins, but DNA does not make proteins directly. Instead, DNA synthesizes messenger RNA (mRNA). In a process called transcription, DNA incorporates the code for the proteins to be synthesized into the mRNA. The mRNA then carries the code to the nucleus of the cell where the code is deciphered by transfer RNA (tRNA) in a process called translation. In translation, amino acids are assembled to make the proteins originally coded for by the DNA. *Id.* at 202-17 (discussing transcription and translation).

24. Proteins can be enzymes, hormones, or structural material. Proteins give organisms their characteristic properties, including color, shape, texture, physical capacities, and many other vital functions necessary for the organism to exist. *Id.* at 64-68.

25. *Making Transgenic Mice*, *supra* note 5, at 590. A new method of making transgenic mice, much simpler than the microinjection of foreign genes, may have been found. This method involves mixing mouse sperm with the DNA of another animal and then artificially inseminating the mouse with foreign DNA by in vitro fertilization. Many scientists, however, are skeptical of this new procedure because the results of the one successful experiment have not yet been duplicated. Barinaga, *Gene-Transfer Method Fails Test*, 246 SCI. 446, 446 (1989). For a description of the microinjection method, see *supra* note 5.

the recipient organism. Transgenic organisms or animals are specifically designed to meet certain human needs; for example, they serve important roles in agriculture, medicine, and genetic research.

### A. Agriculture

In the field of agriculture, biotechnologists seek to improve the quality of livestock by creating larger and leaner animals. Initial transgenic experiments on mice, using genes that code for rat growth hormone, have resulted in the generation of giant mice.<sup>26</sup> Analogous experiments have been done on sheep and pigs, using human or bovine growth hormone.<sup>27</sup> On pigs, transgenic experimentation has resulted in a significant increase in body weight coupled with a decrease in back fat.<sup>28</sup> As a result of this experimentation, scientists expect to be able to create not only larger and leaner livestock, but animals with a greater resistance to disease, a higher degree of fertility, and, in some, an increased dairy production capacity.<sup>29</sup> Scientists also expect to create cows that produce skim milk and chickens that lay low cholesterol eggs.<sup>30</sup>

### B. Medicine

Transgenic animals are also used to produce important medicinal proteins such as human insulin for the treatment of diabetes,<sup>31</sup> human growth hormone for people with growth hormone deficiencies, and tissue plasminogen activator, which is used to break up potentially dangerous blood clots that form after heart attacks or strokes.<sup>32</sup> The use of one particularly interesting

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26. Westphal, *Transgenic Mammals and Biotechnology*, 3 FED'N AM. SOC'Y FOR EXPERIMENTAL BIOLOGY J. 117, 118 (1989).

27. *Id.* Opponents to the use of bovine somatotropin (growth hormone) to stimulate milk production in dairy cows are especially vocal, claiming that the milk produced by the cows is unsafe for the consumer, the treatment is harmful to the cows, and the overproduction of milk is detrimental to the dairy farmer. *Id.*; see also Gibbons, *FDA Publishes Bovine Growth Hormone Data*, 249 SCI. 852, 852-53 (1990) (discussing the safety of bovine human growth hormone). See generally *Hearings on H.R. 1556*, *supra* note 19, at 578 (information on Bovine Growth Hormone (BGH), supplied by the Foundation on Economic Trends (1989)). While conceding that dairy farmers may suffer a negative economic impact, see *infra* text accompanying note 63, proponents claim that the milk is perfectly safe for the consumer because the composition of the milk produced by the treated cows is no different from that of the untreated cows. Grossman, *Genetic Engineering and the Use of Bovine Somatotropin*, 264 J. A.M.A. 1028, 1028 (1990).

28. Westphal, *supra* note 26, at 118-19.

29. Auerbach, *supra* note 3, at 28.

30. Gorner & Kotulak, *Cattle-Cloning Labs Transform the Barnyard*, Chi. Tribune, Apr. 10, 1990, § 1, at 1, col. 2 [hereinafter *Cattle-Cloning*].

31. Auerbach, *supra* note 3, at 27.

32. Dibner, *Factories of Our Future*, 72 CONSUMERS' RES. 15, 15, 16 (1989).

transgene technique has created animals that produce these medicinal proteins in their milk. This is accomplished by transplanting the genes responsible for the production of the desired proteins into an animal cell. The proteins are then produced in great quantity within the animal by the altered host cell, incorporated into the animal's milk,<sup>33</sup> and then separated from the milk and provided to patients. Presently, the cost of human insulin and tissue plasminogen activator is exorbitant;<sup>34</sup> the transgenic approach offers a way to produce large quantities of these costly medicines at more affordable prices. These and other promising medicinal uses<sup>35</sup> of transgenic technology have caused one commentator to describe the experimental animals as pharmaceutical "factories."<sup>36</sup>

Biotechnological production of transgenic animals with human diseases could expedite the development of a cure for diabetes, AIDS,<sup>37</sup> and some forms of cancer.<sup>38</sup> Because transgenic animal models frequently provide a convenient and more affordable device for researchers to study human illnesses at the molecular level, these animals provide a significant contribution to medical research.

### C. Genetic Research

Finally, the study of transgenic animals may someday provide for direct gene therapy to combat various genetic disorders, including disorders of the bone marrow, liver, and central nervous system.<sup>39</sup> In addition, direct gene therapy may prevent or cure various types of hormone and enzyme deficiencies<sup>40</sup> and serious hemoglobinopathies,<sup>41</sup> such as sickle cell anemia and thalassemia.<sup>42</sup> In this application, creation of a transgene mutation in a mouse gene, homologous to the mutation in the affected human gene, would

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33. Andrews, *Administration Backs Bill on Biotechnology*, N.Y. Times, July 28, 1990, § 1, at 30, col. 5 (late ed.).

34. *What Price Mighty Mouse?*, NEW REPUBLIC, May 23, 1988, at 7, 10 [hereinafter *Mighty Mouse*] (tissue plasminogen activator cost estimated at \$2,200 per treatment).

35. The Japanese are currently developing silkworms that produce a hepatitis vaccine. *Id.* at 8.

36. Dibner, *supra* note 32, at 15.

37. Auerbach, *supra* note 3, at 27; *see infra* note 93 (discussing potential for gene therapy to eradicate diseases once believed undefeatable).

38. *See* Anderson, *supra* note 8, at 300.

39. *Id.*

40. *Id.*

41. Mutations in hemoglobin may result in hemoglobinopathies such as sickle cell anemia or thalassemia. Westphal, *supra* note 26, at 120. In these instances, the mutation is genetic and produces an alteration in the protein structure of the hemoglobin, thus impairing its functions by decreasing its affinity for oxygen or reducing the ability of the hemoglobin to transport oxygen. J.D. RAWN, *BIOCHEMISTRY* 142-44 (1983).

42. Westphal, *supra* note 26, at 120.



permit scientists to study various human genetic disorders for which current therapies are inadequate.<sup>43</sup>

## II. THE IMPLICATIONS OF PATENTING LIFE

While the possibilities for advancement in agriculture, farming, and medicine through the use of transgenic animals seem boundless, opponents believe this use of biotechnology should be carefully scrutinized.<sup>44</sup> Members of animal rights and environmental movements, the agriculture industry, religious groups, and certain ethicists have all voiced objection to the use of transgenic animals. Indeed, some believe that biotechnology, if used improperly, "has the power to upset the natural order of the world and to threaten our very humanity."<sup>45</sup> The PTO ruling permitting animal patents has intensified these concerns. This ruling and the Supreme Court's decision in *Diamond v. Chakrabarty*<sup>46</sup> have become significant sources of dispute, spurring a debate so momentous that it has united an unlikely coalition of farmers, environmentalists, animal welfare activists, and religious leaders.

### A. Animal Rights

The genetic engineering of animals has produced an outcry from animal welfare activists who claim that preventing the suffering of animals outweighs the benefits gained from the research. These opponents to animal patenting raise several arguments. First, they assert that transgene experimentation on animals causes undue animal exploitation.<sup>47</sup> Second, they fear that scientists will disregard animal welfare in their pursuit of patents.<sup>48</sup>

43. Friedmann, *Progress Toward Human Gene Therapy*, 244 SCI. 1275, 1275 (1989).

44. Holzman, *Biotechnology's New Strain of Strife*, INSIGHT, Aug. 31, 1987, at 56.

45. *Id.*

46. 447 U.S. 303 (1980). The Court's decision, that live organisms are not outside the scope of patentable inventions, is discussed *infra* at text accompanying notes 94-100.

47. See Pursel, Pinkert, Miller, Bolt, Campbell, Palmiter, Brinster & Hammer, *Genetic Engineering of Livestock*, 244 SCI. 1281, 1285 (1989) [hereinafter Pursel].

48. 134 CONG. REC. S1614 (daily ed. Feb. 29, 1988) (statement of Sen. Hatfield); see also Pursel, *supra* note 47, at 1285 ("Although we have been able to stimulate pig growth and enhance food conversion to protein, it is clear that detrimental effects on the general health of the pigs were also observed."). However, opponents are not altogether certain that experimentation involving transgenic animals is any more detrimental to the animals involved than those animals used in nontransgenic experimentation. See generally Council on Scientific Affairs, *Animals in Research*, 261 J. A.M.A. 3602 (1989) (overview of the use of animals in scientific research for the purpose of medical progress); Smith, Loeb, Evans & Hendee, *Animals in Research and Testing*, 106 ARCHIVES OPHTHALMOLOGY 1184 (1988). One concern of animal rights groups may be that this new avenue of scientific research has created a greater demand for experimental laboratory animals. "It is also clear that *multigenerational* studies are essential to evaluate the physiological effects of transgenes specifically in pigs and perhaps in all livestock animals." Pursel, *supra* note 47, at 1285 (emphasis supplied).

Third, opponents of transgenic experimentation argue that, "because the outcome of transgenic experiments is currently unpredictable, animals produced [from the procedure] will be abnormal at birth, and [will] likely . . . develop novel ailments that veterinary medicine will be unable to [cure]."<sup>49</sup> Fourth, opponents argue that the offspring of transgenic animals will suffer from afflictions similar to those of their parents.<sup>50</sup>

Transgenic experimentation has produced abnormalities in research animals.<sup>51</sup> In the genetic engineering of mice, some pathologies include a shortened lifespan and infertility.<sup>52</sup> Pathological changes in hogs used for genetic engineering experimentation commonly include "lethargy, lameness, uncoordinated gait, exophthalmus, and thickened skin."<sup>53</sup> Other observed detrimental effects to hogs include: "gastric ulceration[s], severe synovitis, degenerative joint disease, pericarditis and endocarditis, cardiomegaly, parakeratosis, nephritis, and pneumonia. In addition, . . . [the] boars [lack] libido."<sup>54</sup>

While animal rights activists take a strong stand against animal patenting, those favoring experimentation on laboratory animals claim that "[w]e long ago decided that sacrificing animals to science . . . is justified."<sup>55</sup> These proponents of animal engineering and animal patenting point out that man has been creating animals for centuries with classical breeding techniques and that the concern for animal welfare has never risen in relation to such breeding.<sup>56</sup> "Harvard's mouse, the result of a more sophisticated intervention,

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49. Taylor, *Patenting Life*, Cong. Res. Serv., Libr. Congress, Order Code IB87222, at 6 (July 20, 1988).

50. *Hearings on H.R. 1556*, *supra* note 19, at 581 (Animal Patenting Fact Sheet submitted by the Foundation on Economic Trends).

[T]here are at present no models capable of predicting the consequence to an organism of even the smallest genetic change . . . . This is the case even when a gene which specifies a known protein (e.g., growth hormone, insulin) is altered, because it is virtually impossible to know in detail all of the interactions in which the changed protein can participate.

*Id.* at 588-89 (letter dated Feb. 19, 1988 from Professor Stuart A. Newman, Ph.D., to Congressman Charles Rose).

51. See Pursel, *supra* note 47, at 1281; see also Ryan, Townes, Reilly, Asakura, Palmiter, Brinster & Behringer, *Human Sickle Hemoglobin in Transgenic Mice*, 247 *Sci.* 566, 566-67 (1990).

52. Pursel, *supra* note 47, at 1284.

53. *Id.*

54. *Id.*

55. *Mighty Mouse*, *supra* note 34, at 9.

56. Taylor, *supra* note 49, at 7. A patent would not be awarded to a particular breed of a species that was improved by a human's use of classical breeding techniques. A patent will be awarded only for an invention that would never occur naturally. Therefore, when a scientist alters the genome of an animal by inserting a human gene, this scientist may be awarded a patent because the result is one that would never occur naturally within the species.

doesn't carry us into a new moral realm."<sup>57</sup> In addition, proponents point out that the legislative restraints on animal research do not exclude the use of animals for some transgenic research.<sup>58</sup> Furthermore, proponents argue that transgenic experimentation may ultimately benefit animals by protecting them from disease.<sup>59</sup>

### B. Agricultural Industry

The agricultural industry will probably face the heaviest economic impact from transgenic experimentation.<sup>60</sup> Presently, there are no patents on farm animals. However, it is likely that superior farm animals will be produced in the future through the transgenic process.<sup>61</sup> Farmers who oppose the patentability of life argue that the process threatens the survival of the family farm. Family farmers unable to afford the new technology would be forced out of business, conceivably allowing well-funded corporations to monopolize the agriculture industry.<sup>62</sup> For instance, the Wisconsin Family Farm Defense Fund, Inc. and the Farmers Union fear that if bovine growth hormone becomes more available through the use of transgenic animals, each cow would produce more milk and fewer cows would be needed to satisfy consumer demand.<sup>63</sup> Under these circumstances, the small family farmer would have difficulty competing in the marketplace:

Even without patented animals the average family farmer in the United States faces an uncertain future. One congressional study

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57. *Mighty Mouse*, *supra* note 34, at 9. Scientific exploitation of animals is a longstanding practice. Animals have suffered in the laboratory and in classical breeding situations through gene manipulations that produce deformities, mutations, or shortened lifespans. With or without human intervention into the genome of an animal, animals will continue to suffer for the sake of science.

58. The two mechanisms providing federal oversight of animal research are the Animal Welfare Act, 7 U.S.C. §§ 2131-2156(h) (1982) (administered by the U.S. Department of Agriculture) and the policy of the Public Health Service, outlined in the National Institutes of Health's Guide for the Care and Use of Laboratory Animals (1985).

59. "[V]eterinarians are trying to induce protective traits in mammals. Major targets for disease resistance include brucellosis, which is blamed for annual cattle losses of at least \$168 million . . . . Other animal ailments under study include blue tongue, foot and mouth disease and bovine leukemia." *Cattle-Cloning*, *supra* note 30, at 14, col. 4.

60. Rifkin, *Patenting New Forms of Animal Life: Is Nature Just a Form of Private Property?*, N.Y. Times, Apr. 26, 1987, § 3, at 2, col. 4.

61. 134 CONG. REC. E2235 (daily ed. June 30, 1988) (statement of Rep. Robert W. Kastenmeier).

62. See 134 CONG. REC. S1620 (daily ed. Feb. 29, 1988). Opponents believe that "[b]y extending patent protection to all forms of animals, the Patent Office has provided the chemical, pharmaceutical and biotechnology companies with the incentive to complete their takeover of American agriculture," thereby displacing the small family farm. Rifkin, *supra* note 60, at 2, col. 4.

63. Auerbach, *supra* note 3, at 32-33.

has already predicted a loss of 1 million farms as a result of factors largely separate from biotechnology. The availability of more efficient livestock poses a difficult challenge for the agricultural community . . . . [There is already an] existing dairy surplus[] and [we] must question how much more we need.<sup>64</sup>

Additionally, unresolved issues such as the timing of royalty payments to the patentee and the possibility of patent infringement by farm animal breeders and dealers trouble many cattle farmers, dairy farmers, and sheep ranchers.<sup>65</sup> Former Commissioner Quigg has suggested that patentees would be entitled to royalties from a farmer and that unauthorized breeding of patented animals, with the intent to increase the numbers of such animals, would constitute patent infringement under existing patent law.<sup>66</sup>

It would be difficult, however, to trace the rights of the patentee to enforce royalty payments because animals, unlike almost any other type of patentable subject matter,<sup>67</sup> reproduce. For instance, if patents presently existed for farm animals, enforcement of existing patent laws against farmers who possess these animals would be unfair because it is not certain whether the offspring of two transgenic animals would either receive the unique trait of its parents, merely some degree of the trait, or none of the trait.<sup>68</sup> What if the farmer bred a transgenic animal with a natural animal? Would this be a patent infringement if the offspring bore the trait? This is one of the unanswered questions.<sup>69</sup>

64. 134 CONG. REC. H7437 (daily ed. Sept. 13, 1988).

65. Rifkin, *supra* note 60, at 2, col. 4.

66. Schneider, *Farmers to Face Patent Fees to Use Gene-Altered Animals*, N.Y. Times, Feb. 6, 1988, at 1, col. 4.

Violation of this [patent] right is a tort analogous to a trespass for which the patent holder may bring a civil action [(35 U.S.C. § 281 (1982))] in a Federal Court. . . . In accordance with general tort theory, liability is also imposed for actively inducing infringement and for contributory infringement by aiding, abetting, encouraging, or contributing to direct infringement by another.

R. CHOATE, W. FRANCIS & R. COLLINS, *PATENT LAW* 583 (3d ed. 1987) (citations omitted). Remedies for patent infringement include injunctive relief, compensatory damages, and attorney's fees. *Id.* at 825.

67. In addition to the Patent Act of 1790 (as amended), there are two patent statutes addressing the subject matter of plants. They are the 1930 Plant Protection Act, 35 U.S.C. § 161 (1982) (extending patent protection to certain asexually reproducing plants), and the Plant Variety Protection Act, 7 U.S.C. §§ 2321-2583 (1982) (enacted in 1970 to provide patent protection to new varieties of sexually reproducing plants).

68. *THE SCIENCE OF LIFE*, *supra* note 4, at 297-316 (discussing patterns of heredity).

69. [A] genetically altered strain of animal is not a single, uniform entity. Biological variability within any population, even one that is relatively homogeneous genetically, guarantees that any modification will be expressed in a variety of different ways in different individuals. . . .

The point of all this is that animals are not built like computers, in which a desired outcome can be achieved by alterations in a well-ordered program. A group of ani-

Opponents to animal patenting argue that the agricultural community does not need livestock patents to provide further incentive and encouragement for improvement within the industry; improved farming efficiency and productivity has been achieved through classical breeding techniques for centuries. Furthermore, farmers have been able to successfully produce improved strains of farm animals throughout this time without the incentive of patents.<sup>70</sup>

On the other hand, proponents of transgenic animal patenting argue that biotechnology is making farmers obsolete regardless of whether the new technologies are patented.<sup>71</sup> They insist that patents be provided to protect investments in research and to ensure the ability of the United States to compete overseas.<sup>72</sup> Moreover, "if market concentration in agricultural industries approaches unhealthy proportions—with or without the aid of patenting—anti-trust law should be vigorously applied. But meanwhile[,] . . . biotechnology . . . [should not be stifled] out of vague fears about big business."<sup>73</sup>

Moreover, supporters of the 1987 PTO ruling argue that it would be unethical *not* to pursue transgenic technology in the agriculture industry.<sup>74</sup> Such research offers hope of combatting world hunger by producing animals capable of being acclimated to harsh environments.<sup>75</sup> Finally, proponents of animal patenting argue that opponents exaggerate the role of transgenic ani-

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mals that carry one or a few altered genes are neither totally identical manufactured entities, nor predictably different in a consistent manner from all other unmodified strains. Changes in DNA are generally inherited, but biological properties associated with such changes are not predictable or necessarily stable.

*Hearings on H.R. 1556, supra* note 19, at 581 (letter dated Feb. 19, 1988 from Professor Stuart A. Newman, Ph.D., to Congressman Charles Rose, discussing support for H.R. 3119).

70. Taylor, *supra* note 49, at 7. The farmer, as a breeder, uses the basic principles of genetics as a tool to manipulate the genotypes of animals to increase the value of the animals.

Putting inherited superiority to work is a major objective of agricultural research. . . . Cultivated plants and domesticated animals are known as cultigens. With increasing precision, man is controlling both the genetics and environments of these cultigens. . . . The genetics of cultigens is not the same as the breeding of cultigens. Animal and plant breeding involve many arts and sciences relating to cultigens, and genetics may be considered the most important of these. There are, of course, successful breeders who have little or no knowledge of the science of genetics. However, today's breeder has come to rely on some pretty sophisticated genetic methods . . . [for developing new and improved strains of domesticated animals].

J. BREWBAKER, AGRICULTURAL GENETICS 1-2 (1964).

71. *Mighty Mouse, supra* note 34, at 9.

72. *Cattle-Cloning, supra* note 30, at 15, col. 4.

73. *Mighty Mouse, supra* note 34, at 9.

74. See *supra* note 59 and accompanying text.

75. Taylor, *supra* note 49, at 7.

mals in agriculture and that the small farmers' fears are without merit.<sup>76</sup>

### C. Religious Organizations

Many religious groups adamantly oppose animal patenting, fearing that reverence and respect for human life, in fact all life created by God, will be diminished.<sup>77</sup> One concern is that when human genes are inserted into animals, and human characteristics are promulgated throughout the animal kingdom, the sanctity of human worth will be undermined.<sup>78</sup> These same groups also worry that human and animal life may be regarded as a commercial commodity, a product of industry, or of human manufacture, thereby undermining the dignity and worth of all life.<sup>79</sup> The Religious Leaders Against Animal Patenting stated that "[t]he gift of life from God, in all its forms and species, should not be regarded solely as if it were a chemical product subject to genetic alteration and patentable for economic benefit."<sup>80</sup> Religious leaders opposed to animal patenting are pressuring Congress to enact measures that will address these concerns.

### D. Environmental Concerns

Transgenics create the possibility for serious ecological disruption. Environmentalists fear that the release of genetically altered animals into the en-

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76. Farm animals differ from experimental animals in that they are raised for economic gain. Thus, the cost and time needed to develop transgenic animals must always be weighed against the anticipated value of the transgenic animals, and the actual value of currently available animals. . . . It has been estimated that it would take three years to produce a small number of transgenic sheep. The cost of the project, using present technology, has been estimated to be approximately three million dollars . . . .

Although . . . impediments [to the production of transgenic farm animals] appear surmountable, they have and will delay the extension of transgenic genetics to farm animals. Moreover, alternative, conventional, approaches toward increasing feed efficiency and milk production have had considerable success (milk production, for example, per cow has doubled in the past 30 years). This success has provided a further disincentive to develop techniques for producing transgenic livestock.

Auerbach, *supra* note 3, at 28 (citations omitted). Other than cost, impediments to the production of transgenic animals include: the technical difficulty in transferring DNA from one organism to another; the possible incompatibility of transgenic mice experimentation for application to farm animals; and the lengthy gestation periods of farm animals in light of the principles of heredity requiring controlled mating and back-crossing of animals in order to produce herds of predictably unique offspring. *Id.*

77. *Hearings on H.R. 1556*, *supra* note 19, at 590 (statement of Religious Leaders Against Animal Patenting).

78. *Id.*

79. *Id.*

80. *Id.*

vironment will contaminate the native gene pools.<sup>81</sup>

The effect of species alteration could also impact the delicate balance of the environment. The creation of new species and the effect of their release into the environment cannot be completely predictable, and should be carefully considered. Animals which are larger and have increased reproductivity could alter the depletion patterns of the ecosystem. Also, if the creation of new improved species leads to the popularization of that animal, valuable native gene pools could be lost.<sup>82</sup>

Depletion of a species' gene pool, one possible consequence of the release of genetically altered animals into the environment, would decrease the genetic variety and engender a common genetic makeup within a particular species. Subsequently, the species' resistance would decrease and cause the species to become susceptible to an epidemic or widespread disease, ultimately placing the species in a high risk for extinction.<sup>83</sup>

The release of transgenic animals into the environment gives rise to several legal issues. Hypothetically, if a particular genetically engineered and patented organism must be contained because of a known harm resulting from its interaction with the environment, should the patentee be responsible for the consequences of its accidental release into the environment? For instance, "[i]f one of Chakrabarty's [oil-eating] bacteria escaped from his laboratory, can he be held responsible for the mischief it causes? If Chakrabarty's bacteria find their way into an oil well or an oil-storage tank, shall he pay drop for drop?"<sup>84</sup>

In addition, the Humane Society fears that the ownership of wildlife may become uncertain with the advent of animal patenting.<sup>85</sup> If patented transgenic animals escaped into the environment, should the patentee have a

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81. A gene pool is the aggregate of all the genes possessed by all the members of a particular population of a species. The frequency of the various genes within a pool may change over time, randomly, or as a result of mutation or natural selection. This is evolution. In the case of natural selection, some genes produce traits that increase population survival in a particular environment, and natural selection facilitates an increased frequency of these certain genes. Likewise, genes that are not helpful, or that are even detrimental, will be reduced in the gene pool and may disappear altogether. *THE SCIENCE OF LIFE*, *supra* note 4, at 321.

82. 133 CONG. REC. S7268 (daily ed. May 28, 1987) (statement of Sen. Hatfield on proposed amendment to H.R. 1827, a supplemental appropriations bill).

83. In addition, a genetically engineered organism may be at a competitive disadvantage to an unaltered organism in the same natural environment. Pimentel, Hunter, LaGro, Efroymsen, Landers, Mervis, McCarthy & Boyd, *Benefits and Risks of Genetic Engineering in Agriculture*, 39 *BIOSCI.* 606, 607 (1989).

84. Kass, *Patenting Life*, 63 *J. PAT. OFF. SOC'Y* 570, 598 (1981).

85. Auerbach, *supra* note 3, at 32.

rightful claim of ownership to the offspring produced as a result of the transgenic animal mating with wildlife?

### E. *What is Human?*

Human beings are not patentable subject matter.<sup>86</sup> Yet, one of the methods used to construct a transgenic animal is to insert human genetic material into the animal's genome.<sup>87</sup> It is unknown whether the resulting hybrid gene structure places the animal within the definition of "human." For example, how much human genetic material in an animal would bring that animal into the confines of humanity? If a fetus is not a human being, would a transgenic fetus be patentable subject matter?

Steven Wise, President of the Animal Legal Defense Fund, Inc., has considered this issue extensively. In testimony before a subcommittee of the House Judiciary Committee, he explained that there is no "fixed genetic definition of a human being."<sup>88</sup> Indeed, no clearly articulated genetic definition of a human being exists to date.<sup>89</sup>

86. See *supra* note 15.

87. Some commentators are repulsed at the notion of producing a creature from the combination of two species—one of them a human being. G. SMITH, *THE NEW BIOLOGY: LAW, ETHICS AND BIOTECHNOLOGY* 3 (1989).

There are two central concerns here: the fear that the product would be viewed as an outcast and not accepted as a member by the species from which it came, and the fear that inappropriate parts of different species could be combined. More specifically, it is commonly thought that a creature with a fair amount of human mentality would be unable to express much if he had a body derived from a wolf or cat.

*Id.* (footnote omitted).

88. *Hearings on H.R. 1556, supra* note 19, at 247-48 (statement of Steven M. Wise, President, Animal Legal Defense Fund, Inc.).

The question has been debated for millennia and a human being has been variously defined as that animal with speech, free will, reason, moral responsibility, thought, politics, consciousness, morality, the ability to cook or stand on two legs or, as postulated by St. Ambrose, to choose celibacy. Yet every definition has been discarded as either underinclusive, as some animals, otherwise believed to be human beings, did not have the relevant characteristic, or overinclusive, as some animals, otherwise believed to be non-human beings, did.

After tens of thousands of years of experience, human beings have generally been able to agree who is and who is not another human being essentially by applying a test similar to that which Justice Stewart used once to identify pornography, which was "I know it when I see it."

*Id.* at 248.

89. *Id.* at 247. An international effort is underway to complete a physical map of the human genome. The National Institutes of Health's (NIH) National Center for Human Genome Research is coordinating the genome project in the United States. NIH plans to spend roughly \$200 million a year on three participating centers. "Each [center] will tackle one of the major objectives of the genome project, such as completing the physical map of one human chromosome or sequencing a model organism." Briefings, *NIH Left Peerless for Genome Centers*, 247 SCI. 1182, 1182 (1990). Although the projected cost of the genome project will be \$3



Because a genetic definition of a human being remains unascertained, many other crucial questions are unanswerable. For instance, would a human being result if "[h]uman hybrids or sub-humans . . . [were] created by splicing human genetic material with that of a lower animal to produce an animal-human hybrid?"<sup>90</sup> Suppose a human is created through recombinant DNA technology to be specifically adapted to a particular environment.<sup>91</sup> If

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billion in 15 years, the rewards will be priceless. Alzheimer's, schizophrenia, heart disease, and cystic fibrosis are among the many diseases that may be eradicated with the completion of the human genome project. "Other medical applications of a genome sequence include an early warning system that may help individuals predisposed to diseases such as alcoholism, colon cancer, and depression." Koshland, *Sequences and Consequences of the Human Genome*, 246 Sci. 189, 189 (1989).

Japan is also attempting to solve the intricacies of the human genome through a project known as the Human Genome Program. The project involves researchers at 30 different institutions and has five focuses, one of which is human genome analysis. Roberts, *Japan Boosts Genome Research*, 246 Sci. 439, 439 (1989). Dangers associated with a map of the human genome remain controverted:

The potential risks from the new technology gained by sequencing the human genome appear, on close examination, to be old problems revisited. Genetic counseling already exists for Down [sic] syndrome, Tay Sachs, and sickle cell anemia. Personal insurance policies already ask for lung x-rays, heart condition tests, and information on such behaviors as smoking. Group insurance is available without [such] test[s]. Fingerprints are not required of the general population but are kept on file for those who commit a crime. The information in the genome adds accuracy and scope to many of these applications but no new or threatening principles. If the higher visibility of the genome project causes a qualitative change, then, of course, new procedures may be needed. [For example if a genome sequence became] a precondition of employment, . . . legislation might be needed . . . .

The argument that dictators would alter genes to convert their enemies is far-fetched. The idea that a Hitler or a Stalin would prefer the engineering of Jews into Aryans or capitalists into communists as cheaper or more satisfying than killing them (as they did) is absurd. We must be vigilant about ethical concerns but not paralyzed by outlandish scenarios.

Koshland, *supra*, at 189. There are, however, those concerned with the use of genetic information to discriminate against individuals attempting to obtain education, employment, or insurance. Responding to this concern, Representative John Conyers has suggested protective federal legislation. Miller, *Genetic Privacy Makes Strange Bedfellows*, 249 Sci. 1368, 1368 (1990). The following describes a possible piece of legislation

designed to regulate the collection, maintenance, use, and dissemination of genetic information gathered from individuals by the federal government and its contractors and grantees. It would forbid agencies to release genetic information without the individual's written consent, except in the case of a medical emergency or a criminal investigation where probable cause or reasonable suspicion has been shown. The bill gives individuals the right to file a suit or [obtain] an injunction against an agency that has released, or is intending to release, such information without permission. It also provides criminal penalties for unauthorized release.

*Id.*

90. *Hearings on H.R. 1556*, *supra* note 19, at 248 (statement of Steven M. Wise, President, Animal Legal Defense Fund, Inc.).

91. Note, *Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Sci-*

such a creature is developed, will it be a human being?<sup>92</sup> This scenario is not as far-fetched as it appears, for it may only be a short time before this possibility must be squarely considered. Presently, the National Institutes of Health (NIH) is conducting a gene therapy experiment. Recently NIH completed a human gene transfer experiment. These landmark experiments were the first of their kind to transfer successfully a foreign gene into the genome of a human being. Although designed to aid in the development of a promising cancer treatment, rather than to improve or perfect the human race, these experiments are man's first attempt to change genetically the human species.<sup>93</sup>

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*ence?*, 16 HASTINGS CONST. L.Q. 221, 222 n.8 (1989) ("Human visitors to a high gravitational field such as that of Jupiter would fare better if they were short-legged or quadrupedal."). See generally Comment, *The Prospect of Private Unauthorized Eugenics and Ten Feet Tall Basketball Players: A Case of Legislative Oversight?*, 1 J. CONTEMP. HEALTH L. & POL'Y 155 (1985) (discussing the need for a uniform federal statute to regulate and limit a private individual's attempts to perform human embryo experiments without authorization).

92. *Hearings on H.R. 1556*, *supra* note 19, at 244 (proposing the same hypothetical); see also B. STABLEFORD, *FUTURE MAN* 108-35 (1984) (chapter, entitled "Engineering People," suggests ways of improving the imperfections of the human body via genetic engineering and also proposes the possibility of adapting man to different living environments, including underwater or outer space, or for modifying man to be more suitable for war). "Cyborgization" is a relatively new term used to describe "the integration of biological systems of man's body with mechanical systems. . . . [I]f a man could be equipped to link up to *machines*, he could effectively acquire a whole range of extended selves by being fitted into machines of many different kinds." G. SMITH, *supra* note 87, at 4 (emphasis in original) (suggesting that cyborgization may be an easier means of increasing human capability than the manipulation of human egg cells).

93. See generally Roberts, *Human Gene Transfer Test Approved*, 243 SCI. 473 (1989); Roberts, *Ethical Questions Haunt New Genetic Technologies*, 243 SCI. 1134 (1989).

The first human gene experiment, involving the transfer of a foreign gene into a human, was fraught with ethical issues. In a 1989 meeting of the Recombinant DNA Advisory Committee (RAC) at the NIH, activist Jeremy Rifkin, attempting to force debate on the larger issue of human genetic engineering and its potential misuse, expressed concern with the implications of this experiment. "Rifkin accused the RAC of ignoring the social and ethical ramifications of human gene therapy, essentially saying that the questions this technology raises are too monumental for an 'elite group of NIH scientists and their handpicked ethical consultants' . . . ." *Id.* But, in the eyes of the scientific community, this first experiment was a success. It proved that foreign genes can be introduced safely and expressed in living human beings. Culliton, *Designing Cells to Deliver Drugs*, 246 SCI. 746, 746 (1989) [hereinafter *Designing Cells*].

While the experiment described above cannot technically be called gene therapy because it involved the use of a foreign gene as a marker and not as a drug, protocols are currently being submitted to NIH to test real human gene therapy. Culliton, *Gene Therapy Proposed*, 247 SCI. 1181, 1181 (1990). In September 1990, the first true human gene therapy experiment was begun and is presently underway. The therapy is designed to give a young child, born without a functioning immune system, a new immune system. Genetically engineered T-lymphocyte cells were infused into the child and will continue to be infused for 18 months with the hope that the cells will be accepted by the patient's body, allowed to produce proper proteins, and replicate. Many scientists are skeptical and critical of this experiment, claiming that the risks involved outweigh any possible benefits. They claim that the gene therapy researchers, W.

### III. CHAKRABARTY AND THE 1987 PTO RULING

The justification for the 1987 PTO rule is derived from the 1980 Supreme Court ruling in *Diamond v. Chakrabarty*,<sup>94</sup> which held that "claims were not outside the scope of patentable inventions merely because they were drawn to 'live organisms'. . . [and] that a live, human-made microorganism<sup>95</sup> is patentable subject matter."<sup>96</sup> Ananda Chakrabarty's oil-consuming bacte-

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French Anderson, R. Michael Blaese, and Steven Rosenberg, acted prematurely and were "driven by ambition and 'not by good science.'" *Scientists Criticize Test of Human Gene Therapy*, Wash. Post, Sept. 21, 1990, at A8, col. 2. See generally Culliton, *Gene Therapy: Into the Home Stretch*, 249 SCI. 974 (1990) (scientific description of the first human gene therapy test); Weiss, *First Human Gene-Therapy Test Begun*, 138 SCI. NEWS 180 (1990) (describing the first human gene therapy test). But cf. Smith, *The Promise of Abundant Life: Patenting a Magnificent Obsession*, 8 J. CONTEMP. L. 85, 86 (1982) ("[W]hat has been dismissed as but a magnificent obsession for power, profits and immortality has in truth a far more intrinsic potential for good and reward for the scientific community and the greater world community.").

Moreover, gene therapy will have direct applications in the field of medicine:

Gene therapy is not just for genetic diseases any more . . . . The idea of curing disease by repairing a broken gene is one of the simplest concepts in medicine. At heart, a gene is nothing more than a chemical set of instructions for the production of a specialized product. Now that genes are routinely isolated and cloned, it ought to be simple to replace a broken gene with a whole one—especially in organs such as blood and bone marrow, which can be easily taken out of the body, modified, and put back in.

*Designing Cells*, *supra*, at 746.

Gene therapy may also prove promising for AIDS patients who need "soluble CD4, the protein that blocks the AIDS virus from penetrating [the] cells." *Id.* People who have had heart attacks and need tissue plasminogen activator (TPA) to prevent artificial blood vessels from developing clots would also benefit from gene therapy, as would patients with emphysema who need the hormone alpha-1 antitrypsin to be delivered to their lungs. In addition, cancer patients and children with critically weak immune systems that lack of a specific functioning gene would be prime candidates for gene therapy, *id.*, as would cystic fibrosis patients. Booth, *Cystic Fibrosis Finding May Enable Gene Therapy*, Wash. Post, Sept. 21, 1990, at A1, col. 5. See generally Culliton, *Gore Tex Organoids and Genetic Drugs*, 246 SCI. 747 (1989); Culliton, *A Genetic Shield to Prevent Emphysema?*, 246 SCI. 750 (1989); Culliton, *ADA Deficiency: A Prime Candidate*, 246 SCI. 751 (1989). For a thorough discussion of the developing technology of human clonal reproduction and its due process and equal protection ramifications, see Note, *Asexual Reproduction and Genetic Engineering: A Constitutional Assessment of the Technology of Cloning*, 47 S. CAL. L. REV. 476 (1974).

94. 447 U.S. 303 (1980).

95. A microorganism differs from a multicellular organism. A microorganism is very small, usually consisting of one or a few cells, such as a bacteria, whereas a multicellular organism, such as a mouse, is comprised of a number of specialized cells. THE SCIENCE OF LIFE, *supra* note 4, at 1090.

96. *Chakrabarty*, 447 U.S. at 304. The ruling of the Supreme Court reversed a decision of the patent examiner, Sidney A. Diamond, who rejected Chakrabarty's patent claim for an oil-eating bacteria on the grounds that living things were not patentable subject matter under 35 U.S.C. § 101 (1982). The Court decided that a claim which otherwise satisfies all of the requirements of patentability may not be denied solely on the grounds that the subject of the claim is living. 447 U.S. at 309, 310, 318. This decision was based upon the Court's broad interpretation of the following provision of the patent laws: "any new and useful . . . manufac-

rium qualified for a patent as a "composition of matter."<sup>97</sup> In so holding, the Court distinguished between man-made and naturally occurring, living and nonliving matter.<sup>98</sup> Presented by the petitioner with a parade of horrors that genetic engineering could one day incite,<sup>99</sup> the Court indicated that it was without competence to decide these arguments: "The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot."<sup>100</sup>

In its 1987 announcement, the PTO broadly interpreted the *Chakrabarty* opinion, declaring that "[t]o the extent that the claimed subject matter is directed to a non-human 'nonnatural occurring manufacture or composition of matter—a product of human ingenuity' . . . such claims will not be rejected under 35 U.S.C. sec. 101 as being directed to nonstatutory subject matter."<sup>101</sup> This ruling raises the possibility that Congress might similarly categorize any living organism as a composition of matter.

The terms "manufacture" and "composition of matter" go back to Jefferson's 1793 patent law, and Congress has retained them without change in all subsequent revisions. . . . Did Jefferson regard a living organism as a mere 'composition of matter'? Certainly in the ordinary sense of these terms, no one should. [The Court] sustains the opinion that Congress intends statutory subject matter to include "anything under the sun made by man." But if so, why did Congress *in fact* make and preserve categorical *distinctions* among the *kinds* of patentable man-made things—processes, machines, manufactures, and "compositions of matter"—distinctions that would be unnecessary if "anything under the sun," so long as of artificial origin, were the sufficient mark of patentable subject matter—of course, along with novelty, utility, and non-obviousness?

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ture, or composition of matter" is the basis upon which a patent is granted. *Id.* at 307-10 (quoting 35 U.S.C. § 101 (1982)). Because *Chakrabarty's* invention was not the result of nature's work, but his own, with characteristics differing from any bacteria occurring naturally, the Court considered the oil-eating bacteria to be patentable subject matter. *Id.* at 309.

The PTO based its subsequent ruling regarding transgenic animal patenting upon the decision of the Board of Patent Appeals in *Ex parte Allen*, 2 U.S.P.Q. 2d (BNA) 1425 (1987). In *Allen*, the Board held that a claim for a method of inducing sterility in oysters, satisfying all other requirements of patentability, would be patentable subject matter under *Chakrabarty*. The Board reasoned that the oyster, although a product of nature, was made sterile through a man-made method for inducing sterility. *Id.* at 1427.

97. *Chakrabarty*, 447 U.S. at 308-14 (discussing the Court's reasoning and statutory construction); see *supra* note 96 (synopsis of Court's ruling).

98. *Chakrabarty*, 447 U.S. at 314.

99. *Id.* at 317 (suggesting that genetic research may threaten human race, spread pollution and disease, result in loss of genetic diversity, and diminish value of human life).

100. *Id.*

101. *Patentable Under § 101*, *supra* note 15, at 664.

And why . . . would Congress enact separate plant patent laws . . . ?<sup>102</sup>

Currently, more than seventy-five animal patent applications have been filed with the Patent and Trademark Office<sup>103</sup> and Congress' immediate attention is needed. To grant transgenic animal patents today may result in the subsequent revocation of such patents if Congress enacts legislation conflicting with the PTO rule.

#### IV. LEGISLATION TAILORED TO THE EMERGING TECHNOLOGY

##### A. *The Need for New Patent Legislation*

Because any legislation in this field will have profound implications for the way future generations perceive and value life, all the issues presented above deserve exhaustive consideration and debate. As technology advances, so must our patent laws.

Although biotechnology is a new and constantly changing field, the basis on which one receives a patent is not. . . . [W]e have reached the point at which we must examine whether our patent system is keeping up with technology. Namely, do the truths that have enabled millions of inventors to obtain patents still hold for the patenting of animals? This is a crucial question that needs further exploration.<sup>104</sup>

Thus, in the legislation that will inevitably develop, the following must be addressed: Will higher organisms remain patentable subject matter? If so, will the regulation of such inventions be addressed before or after they are patented? What specifically will not be patentable subject matter? What is human? What is not human? Will these particular patent applications receive a higher degree of scrutiny than conventional patents? Who will be responsible if non-statutory subject matter is patented?

Unlike most other patented technologies, animals are unique because they reproduce themselves without human intervention. Congress saw the need to enact legislation responding to a similar situation with plants and created two patent laws to deal specifically with their unique qualities.<sup>105</sup> Transgenic animals deserve the same attention.

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102. Kass, *supra* note 84, at 589-90 (emphasis in original).

103. 135 CONG. REC. E3008 (daily ed. Sept. 12, 1989) (statement of Rep. Cardin).

104. *Id.*

105. The Plant Protection Act of 1930, 35 U.S.C. § 161 (1982); The Plant Variety Protection Act of 1970, 7 U.S.C. § 2321-2583 (1982).

### B. Recent Developments in Congress

Congress has been active in its response to the problems presented by animal patents. On August 13, 1987, Representative Rose introduced H.R. 3119, a bill amending the patent laws to prohibit the patenting of genetically altered animals for two years.<sup>106</sup> This bill was also designed to revoke any previously granted patents for transgenic animals. It was defeated in committee by a 2-to-1 vote.<sup>107</sup> On February 29, 1988, Senator Hatfield introduced S. 2111 to rescind the rule promulgated by the PTO. He, too, proposed an amendment to title 35 of the United States Code that would prohibit the patenting of genetically altered or modified animals and revoke any previously granted patents.<sup>108</sup>

On March 22, 1989, Representative Kastenmeier introduced two bills, H.R. 1556 and H.R. 1557, that were identical to two bills introduced in the previous Congress (H.R. 4970, the Transgenic Animal Patent Reform Act, and H.R. 4971, the Transgenic Animal Regulatory Reform Act).<sup>109</sup> H.R. 1557, the Transgenic Animal Regulatory Reform Act, would "regulate the use of genetically-engineered animals in agricultural activities, and for other purposes."<sup>110</sup> H.R. 1556 would limit the rights of animal patentees beyond

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106. 134 CONG. REC. 23,565 (1988) (statement of Rep. Kastenmeier regarding Rep. Rose's proposal for a moratorium).

107. *Id.*

108. S. 2111, 100th Cong., 2d Sess., 134 CONG. REC. 2676-77 (1988).

My decision to offer this legislation is not intended to politicize the Patent Office . . . . But the Patent Office itself admits that it does not take ethical or moral considerations into account when assessing an application for a patent. It is, I believe, the responsibility of Congress to fully consider what kind of technological creativity we wish to encourage through the patenting process, and I believe the giant leap to animal patenting provides us with the specific example we need to conduct such a debate. . . . This [proposed] moratorium is intended to give Congress the opportunity to assess the implications of animal patenting.

*Id.*

109. H.R. 1556 & H.R. 1557, 101st Cong., 1st Sess., 135 CONG. REC. H830 (daily ed. Mar. 22, 1989).

[T]he Transgenic Animal Patent Reform Act addresses the difficult legal and policy issues that arise from the decision of the Patent and Trademark Office to grant patents to genetically altered animals . . . [and] the Transgenic Animal Regulatory Reform Act creates a new regulatory regime for the Federal Government to review work done with transgenic animals. . . . [Both] have their roots in measures I sponsored last Congress, H.R. 4970 and H.R. 4971, respectively.

*Id.*

110. H.R. 1557, 101st Cong., 1st Sess., 135 CONG. REC. H380 (daily ed. Mar. 22, 1989) ("[This bill] develops a regulatory approach for the treatment of transgenic animals."). Section 101 of the bill establishes a Biotechnology Science Coordinating Committee within the Office of Science and Technology Policy. The Committee's functions and purposes are to address the implications and issues concerning genetically engineered animals. The bill would require anyone interested in using genetically engineered animals in agricultural activity to

the restrictions imposed on holders of conventional patents. The bill provides exemptions to small family farmers, certain larger farmers, and to researchers who reproduce these animals for non-commercial purposes.<sup>111</sup>

H.R. 1556, the Transgenic Animal Patent Reform Act, is intended to serve four basic purposes:

[First, it recognizes that] the Patent Office has determined that genetically altered animals are patentable subject matter. Second, the bill clarifies that human beings are not patentable subject matter. Third, the bill authorizes the Commissioner of the Patent and Trademark Office to issue any regulations necessary to regulate the deposit of biological materials. Finally, . . . the bill addresses the thorny question of the scope of a patent on patented transgenic farm animals.<sup>112</sup>

Some of the critical problems addressed in this Comment have not been accounted for in H.R. 1556,<sup>113</sup> the most significant being the lack of a definition for what is human or what is not human. Until this question is addressed, the fear of patenting human life may continue to impede medical advances in genetic engineering.

On September 12, 1989, Representative Cardin introduced a bill providing for "a moratorium on the patenting of animal life until there is a proper regulatory review and approval process in place that takes into consideration environmental, health, safety and biomedical ethical standards on the com-

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obtain a permit from the Secretary of Agriculture. The contents of the permit, including the restrictions and conditions that a permit may contain, are described in section 202(c) and are also subject to the discretion of the Secretary. Several categories of animals are exempted, including genetically engineered animals that are used in biomedical research and that are then released into the wild under the regulation of the Environmental Protection Agency. The bill also provides for initial use permits, expanded use permits, commercial use permits, waivers and extensions of permits, and liabilities and penalties for failure to comply with the bill's requirements. *Id.*

111. H.R. 1557, 101st Cong., 1st Sess. (1989). Section 2, entitled Infringement of Patent, would amend 35 U.S.C. § 271 (1982) by adding the following subsection:

(h)(1) It shall not be an act of infringement for a person whose occupation is farming to reproduce a patented transgenic farm animal through breeding, use such animal in the farming operation, or sell such animal or the offspring of such animal.

(2) Notwithstanding the provisions of paragraph (1), it shall be an act of infringement for a person to sell the germ cells, semen, or embryos of a patented transgenic farm animal.

(3) for purposes of paragraphs (1) and (2)—

(A) the term "transgenic farm animal" means a farm animal whose germ cells contain genetic material originally derived from another animal other than the parent of the farm animal; and

(B) the term "farm animal" means any animal used or intended for use as food or fiber.

112. H.R. 1557, 101st Cong., 1st Sess., 135 CONG. REC. H830 (daily ed. Mar. 22, 1989).

113. See *supra* text accompanying notes 86-93.

mercialization of an animal."<sup>114</sup> His bill would put a temporary halt to the patenting of animals, not out of fear of progress, but out of "concerns about the effect patenting of animal life could have on our society."<sup>115</sup> On February 26, 1990, Senator Hatfield submitted S. 2169 to the Senate for consideration. This bill would amend title 35 of the United States Code to impose a five-year moratorium on the granting of patents for transgenic animals. The purpose of the moratorium is to allow Congress time to establish a federal regulatory process to deal with issues arising in connection with animal patenting. He believes that direct congressional oversight of such far-reaching technology is critical if Congress is to act responsibly in its representative capacity.<sup>116</sup>

At this time, a moratorium is the most appropriate way to address the problems associated with transgenic animal patenting. Biotechnology has prompted the imagination of the scientific world and may make hopes for solving the mysteries of humanity an imminent reality.<sup>117</sup> While Congress'

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114. H.R. 3247, 101st Cong., 1st Sess., 135 CONG. REC. E3008 (daily ed. Sept. 12, 1989).

115. *Id.* Representative Cardin would like to see further exploration of the implications of animal patenting on our health, safety and environment. . . . [I]t was the PTO, not Congress, that decided in 1987 that nonhuman animals constituted patentable subject matter. The PTO stepped in to fill the void. But it is time for Congress to become more involved in the debate. A moratorium would provide us with the necessary time to determine whether or not we need to make improvements in our patent law to deal directly with the patenting of animals.

*Id.*

116. S. 2169, 101st Cong., 2d Sess., 136 CONG. REC. S1611 (daily ed. Feb. 26, 1990). In addition, Senator Hatfield believes the PTO is incapable of dealing with these issues and that it is the responsibility of Congress to consider the technology and its ramifications before it delegates any authority to the PTO to do so. His declared intention is not to put a halt to animal patenting ultimately, but to determine a way to use this new technology responsibly. He noted that "the patenting of animals blurs the distinction between man's work and God's work in a way . . . [that] is tremendously dangerous." *Id.* Senator Hatfield addressed economic, environmental, ethical and governmental concerns specifically:

In economic terms, this controversial patent policy transforms the genetic makeup of the biotic community from a common heritage of us all—to the private preserve of the major corporations. Major biotechnology and chemical corporations will increasingly compete for control and ownership of the gene pool of animal species, patenting those creatures that they can successfully genetically engineer. . . . By genetically altering a major livestock species—and then patenting that creation—a corporation could become the sole controller of that species. Farmers would be forced to pay the corporation patent fees every time they bred the species, or sold part of their herd. . . . Researchers and small scientific institutions could also be devastated by animal patenting as they would be forced to pay patent fees on genetically engineered laboratory animals.

*Id.* He also discussed other issues associated with animal research, religious convictions, and the possibility of patenting the human form. *Id.*

117. See, e.g., *Hearings on H.R. 1556*, *supra* note 19, at 593 (statement of Cy Carpenter, President of the National Farmers Union).



attention should be directed immediately to this issue, Congress is presently not ready to resolve the extensive ramifications of animal patenting and a moratorium would allow for the type of sophisticated deliberation the matter deserves.

#### IV. CONCLUSION

Transgenic experimentation may prove to be the key that unlocks the secret of life. Where it takes the scientific world will depend largely on what limitations are placed upon the scientific and patenting processes by the legal and scientific professions. The unique problems associated with transgenic animals are replete with significant legal and ethical obstacles. Before the question, whether to patent animals, can be answered definitively by Congress, fundamental issues must be resolved. "Such a decision, one that likely affronts the philosophical, theological, or ethical beliefs of the majority of Americans, should be made only after the most searching, sensitive, and comprehensive of debates."<sup>118</sup> Certainly, biotechnology will continue to uncover the secrets of life with or without patent protection, and there may come a time when the decision of whether to patent animals appears simplistic. "But Congress should not *accelerate* the creation and production of transgenic animals at a time when the debate of these serious issues is just taking hold, and most of America remains to be informed."<sup>119</sup>

*Diana A. Mark*

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118. *Id.* at 256 (statement of Steven M. Wise, President, Animal Legal Defense Fund, Inc.).

119. *Id.* (emphasis in original).